

## General

### Guideline Title

(1) Gonococcal infections. In: Sexually transmitted diseases treatment guidelines, 2010. (2) Update to CDC's sexually transmitted diseases treatment guidelines, 2010: oral cephalosporins no longer a recommended treatment for gonococcal infections.

### Bibliographic Source(s)

Centers for Disease Control and Prevention (CDC). Gonococcal infections. In: Sexually transmitted diseases treatment guidelines, 2010 [Erratum appears in MMWR Recomm Rep. 2011 Jan 14;60(1):18]. MMWR Recomm Rep. 2010 Dec 17;59(RR-12):49-55.

Centers for Disease Control and Prevention (CDC). Update to CDC's sexually transmitted diseases treatment guidelines, 2010: oral cephalosporins no longer a recommended treatment for gonococcal infections. MMWR Morb Mortal Wkly Rep. 2012 Aug 10;61:590-4. [11 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

*Note from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC):* On August 10, 2012, the CDC released an addendum to their 2010 recommendation for treatment of gonococcal infections. This report, which uses data from CDC's Gonococcal Isolate Surveillance Project (GISP), describes laboratory evidence of declining cefixime susceptibility among urethral *Neisseria gonorrhoeae* isolates collected in the United States during 2006–2011. Based on this data, CDC no longer recommends cefixime at any dose as a first-line regimen for treatment of gonococcal infections. The updated recommendations are presented below, followed by the recommendations from the original 2010 guideline.

#### 2012 Addendum

For treatment of uncomplicated urogenital, anorectal, and pharyngeal gonorrhea, CDC recommends combination therapy with a single intramuscular dose of ceftriaxone 250 mg plus either a single dose of azithromycin 1 g orally or doxycycline 100 mg orally twice daily for 7 days.

#### Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum

##### *Recommended Regimen*

- Ceftriaxone 250 mg in a single intramuscular dose  
PLUS

- Azithromycin 1 g orally in a single dose or doxycycline 100 mg orally twice daily for 7 days\*

#### *Alternative Regimens*

If ceftriaxone is not available:

- Cefixime 400 mg in a single oral dose  
PLUS
- Azithromycin 1 g orally in a single dose or doxycycline 100 mg orally twice daily for 7 days\*  
PLUS
- Test-of-cure in 1 week

If the patient has severe cephalosporin allergy:

- Azithromycin 2 g in a single oral dose  
PLUS
- Test-of-cure in 1 week

### Uncomplicated Gonococcal Infections of the Pharynx

#### *Recommended Regimen*

- Ceftriaxone 250 mg in a single intramuscular dose  
PLUS
- Azithromycin 1 g orally in a single dose or doxycycline 100 mg orally twice daily for 7 days\*

\*Because of the high prevalence of tetracycline resistance among Gonococcal Isolate Surveillance Project (GISP) isolates, particularly those with elevated minimum inhibitory concentrations to cefixime, the use of azithromycin as the second antimicrobial is preferred.

Clinicians who diagnose gonorrhea in a patient with persistent infection after treatment (treatment failure) with the recommended combination therapy regimen should culture relevant clinical specimens and perform antimicrobial susceptibility testing of *N. gonorrhoeae* isolates. Phenotypic antimicrobial susceptibility testing should be performed using disk diffusion, Etest (BioMérieux, Durham, NC), or agar dilution. Data currently are limited on the use of nucleic acid amplification test (NAAT)-based antimicrobial susceptibility testing for genetic mutations associated with resistance in *N. gonorrhoeae*. The laboratory should retain the isolate for possible further testing. The treating clinician should consult an infectious disease specialist, a sexually transmitted disease/human immunodeficiency virus (STD/HIV) Prevention Training Center (<http://www.nmptc.org>), or CDC (telephone: 404-639-8659) for treatment advice, and report the case to CDC through the local or state health department within 24 hours of diagnosis. A test-of-cure should be conducted 1 week after re-treatment, and clinicians should ensure that the patient's sex partners from the preceding 60 days are evaluated promptly with culture and treated as indicated.

When ceftriaxone cannot be used for treatment of urogenital or rectal gonorrhea, two alternative options are available: cefixime 400 mg orally plus either azithromycin 1 g orally or doxycycline 100 mg twice daily orally for 7 days if ceftriaxone is not readily available, or azithromycin 2 g orally in a single dose if ceftriaxone cannot be given because of severe allergy. If a patient with gonorrhea is treated with an alternative regimen, the patient should return 1 week after treatment for a test-of-cure at the infected anatomic site. The test-of-cure ideally should be performed with culture or with a NAAT for *N. gonorrhoeae* if culture is not readily available. If the NAAT is positive, every effort should be made to perform a confirmatory culture. All positive cultures for test-of-cure should undergo phenotypic antimicrobial susceptibility testing. Patients who experience treatment failure after treatment with alternative regimens should be treated with ceftriaxone 250 mg as a single intramuscular dose and azithromycin 2 g orally as a single dose and should receive infectious disease consultation. The case should be reported to CDC through the local or state health department.

For all patients with gonorrhea, every effort should be made to ensure that the patients' sex partners from the preceding 60 days are evaluated and treated for *N. gonorrhoeae* with a recommended regimen. If a heterosexual partner of a patient cannot be linked to evaluation and treatment in a timely fashion, then expedited partner therapy should be considered, using oral combination antimicrobial therapy for gonorrhea (cefixime 400 mg and azithromycin 1 g) delivered to the partner by the patient, a disease investigation specialist, or through a collaborating pharmacy.

The capacity of laboratories in the United States to isolate *N. gonorrhoeae* by culture is declining rapidly because of the widespread use of NAATs for gonorrhea diagnosis, yet it is essential that culture capacity for *N. gonorrhoeae* be maintained to monitor antimicrobial resistance

trends and determine susceptibility to guide treatment following treatment failure. To help control gonorrhea in the United States, health-care providers must maintain the ability to collect specimens for culture and be knowledgeable of laboratories to which they can send specimens for culture. Health-care systems and health departments must support access to culture, and laboratories must maintain culture capacity or develop partnerships with laboratories that can perform culture.

Treatment of patients with gonorrhea with the most effective therapy will limit the transmission of gonorrhea, prevent complications, and likely will slow emergence of resistance. However, resistance to cephalosporins, including ceftriaxone, is expected to emerge. Reinvestment in gonorrhea prevention and control is warranted. New treatment options for gonorrhea are urgently needed.

## 2010 Guideline

*Note from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC):* When more than one therapeutic regimen is recommended, the sequence is alphabetized unless the choices for therapy are prioritized based on efficacy, convenience, or cost. For sexually transmitted diseases (STDs) with more than one recommended regimen, almost all regimens have similar efficacy and similar rates of intolerance or toxicity unless otherwise specified.

## Gonococcal Infections in Adolescents and Adults

In the United States, an estimated 700,000 new *N. gonorrhoeae* infections occur each year. Gonorrhea is the second most commonly reported bacterial STD. The majority of urethral infections caused by *N. gonorrhoeae* among men produce symptoms that cause them to seek curative treatment soon enough to prevent serious sequelae, but treatment might not be soon enough to prevent transmission to others. Among women, gonococcal infections might not produce recognizable symptoms until complications (e.g., pelvic inflammatory disease [PID]) have occurred. PID can result in tubal scarring that can lead to infertility or ectopic pregnancy.

The prevalence of gonorrhea varies widely among communities and populations; health-care providers should consider local gonorrhea epidemiology when making screening decisions. Although widespread screening is not recommended because gonococcal infections among women are frequently asymptomatic, targeted screening of young women (i.e., those aged <25 years) at increased risk for infection is a primary component of gonorrhea control in the United States. For sexually active women, including those who are pregnant, the U.S. Preventive Services Task Force (USPSTF) recommends that clinicians provide gonorrhea screening only to those at increased risk for infection (e.g., women with previous gonorrhea infection, other STDs, new or multiple sex partners, and inconsistent condom use; those who engage in commercial sex work and drug use; women in certain demographic groups; and those living in communities with a high prevalence of disease). The USPSTF does not recommend screening for gonorrhea in men and women who are at low risk for infection.

## Diagnostic Considerations

Because of its high specificity (>99%) and sensitivity (>95%), a Gram stain of a male urethral specimen that demonstrates polymorphonuclear leukocytes with Gram-negative intracellular diplococci (GNID) can be considered diagnostic for infection with *N. gonorrhoeae* in symptomatic men. However, because of lower sensitivity, a negative Gram stain should not be considered sufficient for ruling out infection in asymptomatic men. In addition, Gram stain of endocervical specimens, pharyngeal, or rectal specimens also are not sufficient to detect infection and, therefore, are not recommended. Specific testing for *N. gonorrhoeae* is recommended because of the increased utility and availability of highly sensitive and specific testing methods and because a specific diagnosis might enhance partner notification.

Specific diagnosis of infection with *N. gonorrhoeae* may be performed by testing endocervical, vaginal, urethral (men only), or urine specimens. Culture, nucleic acid hybridization tests, and NAATs are available for the detection of genitourinary infection with *N. gonorrhoeae*. Culture and nucleic acid hybridization tests require female endocervical or male urethral swab specimens. NAATs allow testing of the widest variety of specimen types including endocervical swabs, vaginal swabs, urethral swabs (men), and urine (from both men and women), and they are U.S. Food and Drug Administration (FDA)-cleared for use. However, product inserts for each NAAT vendor must be carefully examined, because specimen types that are FDA-cleared for use vary by test. NAAT tests are not FDA-cleared for use in the rectum, pharynx, and conjunctiva; however, some public and private laboratories have established performance specifications for using NAAT with rectal and pharyngeal swab specimens, thereby allowing results to be used for clinical management. Laboratories that establish performance specifications for the use of NAATs with nongenital specimens must ensure that specificity is not compromised by cross-reaction with nongonococcal *Neisseria* species. The sensitivity of NAATs for the detection of *N. gonorrhoeae* in genital and nongenital anatomic sites is superior to culture but varies by NAAT type.

Because nonculture tests cannot provide antimicrobial susceptibility results, in cases of suspected or documented treatment failure, clinicians should perform both culture and antimicrobial susceptibility testing.

All persons found to have gonorrhea should be tested for other STDs, including chlamydia, syphilis, and HIV.

## Dual Therapy for Gonococcal and Chlamydial Infections

Patients infected with *N. gonorrhoeae* frequently are coinfecting with *Chlamydia trachomatis*; this finding has led to the recommendation that patients treated for gonococcal infection also be treated routinely with a regimen that is effective against uncomplicated genital *C. trachomatis* infection. Because most gonococci in the United States are susceptible to doxycycline and azithromycin, routine cotreatment might also hinder the development of antimicrobial-resistant *N. gonorrhoeae*. Limited data suggest that dual treatment with azithromycin might enhance treatment efficacy for pharyngeal infection when using oral cephalosporins.

#### Antimicrobial-Resistant *N. gonorrhoeae*

Gonorrhea treatment is complicated by the ability of *N. gonorrhoeae* to develop resistance to antimicrobial therapies. Quinolone-resistant *N. gonorrhoeae* strains are now widely disseminated throughout the United States and the world. As of April 2007, quinolones are no longer recommended in the United States for the treatment of gonorrhea and associated conditions, such as PID. Consequently, only one class of antimicrobials, the cephalosporins, is recommended and available for the treatment of gonorrhea in the United States. The CDC website (<http://www.cdc.gov/std/gisp> ) and state health departments can provide the most current information.

Most of the treatment failures resulting from use of oral cephalosporins have been reported from Asian countries, although one possible case was reported in Hawaii in 2001. To ensure appropriate antibiotic therapy, clinicians should ask patients testing positive for gonorrhea about recent travel to and sexual activity in these countries.

Decreased susceptibility of *N. gonorrhoeae* to cephalosporins and other antimicrobials is expected to continue to spread; therefore, state and local surveillance for antimicrobial resistance is crucial for guiding local therapy recommendations. GISP, which samples approximately 3% of all U.S. men who have gonococcal infections, is a mainstay of surveillance. However, surveillance by clinicians also is critical. Clinicians who diagnose *N. gonorrhoeae* infection in a patient with suspected cephalosporin treatment failure should perform culture and susceptibility testing of relevant clinical specimens, consult a specialist for guidance in clinical management, and report the case to CDC through state and local public health authorities. Health departments should prioritize partner notification and contact tracing of patients with *N. gonorrhoeae* infection thought to be associated with cephalosporin treatment failure or associated with patients whose isolates demonstrate decreased susceptibility to cephalosporin.

#### Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum\*

##### *Recommended Regimens*

- Ceftriaxone 250 mg intramuscularly (IM) in a single dose  
OR IF NOT AN OPTION
- Cefixime 400 mg orally in a single dose  
OR
- Single-dose injectable cephalosporin regimens  
PLUS
- Azithromycin 1 g orally in a single dose  
OR
- Doxycycline 100 mg orally twice a day for 7 days

\*These recommendations have been replaced by the recommendations in the 2012 addendum, above.

To maximize compliance with recommended therapies, medications for gonococcal infections should be dispensed on site. Ceftriaxone in a single injection of 250 mg provides sustained, high bactericidal levels in the blood. Extensive clinical experience indicates that ceftriaxone is safe and effective for the treatment of uncomplicated gonorrhea at all anatomic sites, curing 99.2% of uncomplicated urogenital and anorectal and 98.9% of pharyngeal infections in published clinical trials. A 250-mg dose of ceftriaxone is now recommended over a 125-mg dose given the 1) increasingly wide geographic distribution of isolates demonstrating decreased susceptibility to cephalosporins in vitro, 2) reports of ceftriaxone treatment failures, 3) improved efficacy of ceftriaxone 250 mg in pharyngeal infection (which is often unrecognized), and 4) the utility of having a simple and consistent recommendation for treatment regardless of the anatomic site involved.

A 400-mg oral dose of cefixime does not provide as high, nor as sustained, a bactericidal level as that provided by the 250-mg dose of ceftriaxone. In published clinical trials, the 400-mg dose cured 97.5% of uncomplicated urogenital and anorectal and 92.3% of pharyngeal gonococcal infections. Although cefixime can be administered orally, this advantage is offset by the limited efficacy of cefixime (as well as other oral cephalosporins) for treating gonococcal infections of the pharynx. Providers should inquire about oral sexual exposure and, if reported, treat these patients with ceftriaxone because of this drug's well documented efficacy in treating pharyngeal infection.

Single-dose injectable cephalosporin regimens (other than ceftriaxone 250 mg IM) that are safe and highly effective against uncomplicated urogenital and anorectal gonococcal infections include cefizoxime (500 mg, administered IM), cefoxitin (2 g, administered IM with probenecid 1 g orally), and cefotaxime (500 mg, administered IM). None of the injectable cephalosporins offer any advantage over ceftriaxone for urogenital infection, and efficacy for pharyngeal infection is less certain.

### Alternative Regimens

Several other antimicrobials are active against *N. gonorrhoeae*, but none have substantial advantages over the recommended regimens, and they should not be used if pharyngeal infection is suspected. Some evidence suggests that cefpodoxime 400 mg orally can be considered an alternative in the treatment of uncomplicated urogenital gonorrhea; this regimen meets the minimum efficacy criteria for alternative regimens for urogenital infection. In one clinical trial, cefpodoxime 400 mg orally was found to have a urogenital and rectal cure rate of 96.6%, but the efficacy of cefpodoxime 400 mg orally at the pharyngeal site was poor. Gonococcal strains with decreased susceptibility to oral cephalosporins have been reported in the United States. With a cure rate of 96.5% for urogenital and rectal infection, cefpodoxime proxetil 200 mg orally meets the criteria for an alternative regimen; however, its use is not advised because of concerns about the pharmacodynamics of cefpodoxime using this dose. Efficacy in treating pharyngeal infection with cefpodoxime 200 mg is unsatisfactory, as with cefpodoxime at the 400-mg dose.

Treatment with cefuroxime axetil 1 g orally meets the criteria for minimum efficacy as an alternative regimen for urogenital and rectal infection, but the pharmacodynamics of cefuroxime axetil 1 g orally are less favorable than those of cefpodoxime 400 mg, cefixime 400 mg, or ceftriaxone 125 mg. The efficacy of cefuroxime axetil 1 g orally in treating pharyngeal infection is poor.

Spectinomycin, which is useful in persons who cannot tolerate cephalosporins, is expensive, must be injected, and is not available in the United States (updates available at: <http://www.cdc.gov/std/treatment/default.htm>). However, it has been effective in published clinical trials, curing 98.2% of uncomplicated urogenital and anorectal gonococcal infections. Spectinomycin has poor efficacy against pharyngeal infection.

Azithromycin 2 g orally is effective against uncomplicated gonococcal infection, but concerns over the ease with which *N. gonorrhoeae* can develop resistance to macrolides should restrict its use to limited circumstances. Although azithromycin 1 g meets alternative regimen criteria, it is not recommended because several studies have documented treatment failures, and concerns about possible rapid emergence of antimicrobial resistance with the 1-g dose of azithromycin are even greater than with the 2-g dose. *N. gonorrhoeae* in the United States is not adequately susceptible to penicillins, tetracyclines, and older macrolides (e.g., erythromycin) for these antimicrobials to be recommended.

### Uncomplicated Gonococcal Infections of the Pharynx

Most gonococcal infections of the pharynx are asymptomatic and can be relatively common in some populations. Gonococcal infections of the pharynx are more difficult to eradicate than infections at urogenital and anorectal sites. Few antimicrobial regimens, including those involving oral cephalosporins, can reliably cure >90% of gonococcal pharyngeal infections. Providers should ask their patients about oral sexual exposure; if reported, patients should be treated with a regimen with acceptable efficacy against pharyngeal infection. Chlamydial coinfection of the pharynx is unusual; however, because coinfection at genital sites sometimes occurs, treatment for both gonorrhea and chlamydia is recommended.

#### Recommended Regimens

- Ceftriaxone 250 mg IM in a single dose  
PLUS
- Azithromycin 1 g orally in a single dose  
OR
- Doxycycline 100 mg orally twice a day for 7 days

### Follow-Up

Patients diagnosed with uncomplicated gonorrhea who are treated with any of the recommended or alternative regimens do not need a test-of-cure (i.e., repeat testing 3–4 weeks after completing therapy). Patients who have symptoms that persist after treatment should be evaluated by culture for *N. gonorrhoeae*, and any gonococci isolated should be tested for antimicrobial susceptibility. Persistent urethritis, cervicitis, or proctitis also might be caused by *C. trachomatis* or other organisms.

*N. gonorrhoeae* infection is prevalent among patients who have been diagnosed with and treated for gonorrhea in the preceding several months. Most infections result from reinfection rather than treatment failure, indicating a need for improved patient education and referral of sex partners. Clinicians should advise patients with gonorrhea to be retested 3 months after treatment. If patients do not seek medical care for retesting in 3

months, providers are encouraged to test these patients whenever they next seek medical care within the following 12 months, regardless of whether the patients believe that their sex partners were treated. Retesting is distinct from test-of-cure to detect therapeutic failure, which is not recommended.

## Management of Sex Partners

Effective clinical management of patients with treatable STDs requires treatment of the patients' recent sex partners to prevent reinfection and curtail further transmission. Patients should be instructed to refer their sex partners for evaluation and treatment. Sex partners of patients with *N. gonorrhoeae* infection whose last sexual contact with the patient was within 60 days before onset of symptoms or diagnosis of infection in the patient should be evaluated and treated for *N. gonorrhoeae* and *C. trachomatis* infections. If a patient's last sexual intercourse was >60 days before onset of symptoms or diagnosis, the patient's most recent sex partner should be treated. Patients should be instructed to abstain from sexual intercourse until therapy is completed and until they and their sex partners no longer have symptoms.

For heterosexual patients with gonorrhea whose partners' treatment cannot be ensured or is unlikely, delivery of antibiotic therapy for gonorrhea (as well as for chlamydia) by the patients to their partners can be considered (see the CDC guideline Clinical Prevention Guidance). Use of this approach should always be accompanied by efforts to educate partners about symptoms and to encourage partners to seek clinical evaluation. For male patients informing female partners, educational materials should include information about the importance of seeking medical evaluation for PID (especially if symptomatic). Possible undertreatment of PID in female partners and possible missed opportunities to diagnose other STDs are of concern and have not been evaluated in comparison with patient-delivered therapy and partner referral. This approach should not be considered a routine partner management strategy in men who have sex with men (MSM) because of the high risk for coexisting undiagnosed STDs or human immunodeficiency virus (HIV) infection.

## Special Considerations

### *Allergy, Intolerance, and Adverse Reactions*

Reactions to first generation cephalosporins occur in approximately 5%–10% of persons with a history of penicillin allergy and occur less frequently with third-generation cephalosporins. In those persons with a history of penicillin allergy, the use of cephalosporins should be contraindicated only in those with a history of a severe reaction to penicillin (e.g., anaphylaxis, Stevens Johnson syndrome, and toxic epidermal necrolysis).

Because data are limited regarding alternative regimens for treating gonorrhea among persons who have severe cephalosporin allergy, providers treating such patients should consult infectious disease specialists. Azithromycin 2 g orally is effective against uncomplicated gonococcal infection, but because of concerns over emerging antimicrobial resistance to macrolides, its use should be limited. Cephalosporin treatment following desensitization is impractical in most clinical settings.

### *Pregnancy*

As with other patients, pregnant women infected with *N. gonorrhoeae* should be treated with a recommended or alternate cephalosporin. Because spectinomycin is not available in the United States, azithromycin 2 g orally can be considered for women who cannot tolerate a cephalosporin. Either azithromycin or amoxicillin is recommended for treatment of presumptive or diagnosed *C. trachomatis* infection during pregnancy (see the CDC guideline Chlamydial Infections).

### *HIV Infection*

Patients who have gonococcal infection and also are infected with HIV should receive the same treatment regimen as those who are HIV negative.

### *Suspected Cephalosporin Treatment Failure or Resistance*

Suspected treatment failure has been reported among persons receiving oral and injectable cephalosporins. Therefore, clinicians of patients with suspected treatment failure or persons infected with a strain found to demonstrate in vitro resistance should consult an infectious disease specialist, conduct culture and susceptibility testing of relevant clinical specimens, retreat with at least 250 mg of ceftriaxone IM or intravenously (IV), ensure partner treatment, and report the situation to CDC through state and local public health authorities.

## Gonococcal Conjunctivitis

In the only published study of the treatment of gonococcal conjunctivitis among U.S. adults, all 12 study participants responded to a single 1-g IM injection of ceftriaxone.

### *Recommended Regimen*



- Ceftriaxone 1 g IM in a single dose

Consider lavage of the infected eye with saline solution once. Persons treated for gonococcal conjunctivitis should be treated presumptively for concurrent *C. trachomatis* infection.

#### *Management of Sex Partners*

Patients should be instructed to refer their sex partners for evaluation and treatment (see Management of Sex Partners, above).

#### Disseminated Gonococcal Infection (DGI)

DGI frequently results in petechial or pustular acral skin lesions, asymmetrical arthralgia, tenosynovitis, or septic arthritis. The infection is complicated occasionally by perihepatitis and rarely by endocarditis or meningitis. Some strains of *N. gonorrhoeae* that cause DGI can cause minimal genital inflammation. No recent studies have been published on the treatment of DGI.

#### *Treatment*

Hospitalization is recommended for initial therapy, especially for patients who might not comply with treatment, for those in whom diagnosis is uncertain, and for those who have purulent synovial effusions or other complications. Examination for clinical evidence of endocarditis and meningitis should be performed. Persons treated for DGI should be treated presumptively for concurrent *C. trachomatis* infection.

##### *Recommended Regimen*

- Ceftriaxone 1 g IM or IV every 24 hours

##### *Alternative Regimens*

- Cefotaxime 1 g IV every 8 hours  
OR
- Cefizoxime 1 g IV every 8 hours

All of the preceding regimens should be continued for 24 to 48 hours after improvement begins, at which time therapy can be switched to cefixime 400 mg orally twice daily to complete at least 1 week of antimicrobial therapy. No treatment failures have been reported with the recommended regimens.

#### *Management of Sex Partners*

Gonococcal infection frequently is asymptomatic in sex partners of patients who have DGI. As with uncomplicated gonococcal infections, patients should be instructed to refer their sex partners for evaluation and treatment.

#### Gonococcal Meningitis and Endocarditis

##### *Recommended Regimen*

- Ceftriaxone 1-2 g IV every 12 hours

Therapy for meningitis should be continued for 10 to 14 days; therapy for endocarditis should be continued for at least 4 weeks. Treatment of complicated DGI should be undertaken in consultation with an infectious disease specialist.

#### *Management of Sex Partners*

Patients should be instructed to refer their sex partners for evaluation and treatment (see Management of Sex Partners, above).

#### Gonococcal Infections among Infants

Gonococcal infection among infants usually is caused by exposure to infected cervical exudate at birth. It is usually an acute illness that manifests 2 to 5 days after birth. The prevalence of infection among infants depends on the prevalence of infection among pregnant women, whether pregnant women are screened for gonorrhea, and whether newborns receive ophthalmia prophylaxis. The most severe manifestations of *N. gonorrhoeae* infection in newborns are ophthalmia neonatorum and sepsis, which can include arthritis and meningitis. Less severe manifestations include rhinitis, vaginitis, urethritis, and reinfection at sites of fetal monitoring.

#### Ophthalmia Neonatorum Caused by *N. gonorrhoeae*

Although *N. gonorrhoeae* causes ophthalmia neonatorum relatively infrequently in the United States, identifying and treating this infection is especially important because ophthalmia neonatorum can result in perforation of the globe of the eye and blindness.

### Diagnostic Considerations

Infants at increased risk for gonococcal ophthalmia are those who do not receive ophthalmia prophylaxis and those whose mothers have had no prenatal care or whose mothers have a history of STDs or substance abuse. Gonococcal ophthalmia is strongly suspected when intracellular gram-negative diplococci are identified in conjunctival exudate, justifying presumptive treatment for gonorrhea after appropriate cultures for *N. gonorrhoeae* are obtained. Appropriate chlamydial testing should be done simultaneously. Presumptive treatment for *N. gonorrhoeae* might be indicated for newborns who are at increased risk for gonococcal ophthalmia and who have increased white blood cells (WBCs) (but not gonococci) in a Gram-stained smear of conjunctival exudate.

In all cases of neonatal conjunctivitis, conjunctival exudates should be cultured for *N. gonorrhoeae* and tested for antibiotic susceptibility before a definitive diagnosis is made. A definitive diagnosis is vital because of the public health and social consequences of a diagnosis of gonorrhea. Nongonococcal causes of neonatal ophthalmia include *Moraxella catarrhalis* and other *Neisseria* species that are indistinguishable from *N. gonorrhoeae* on Gram-stained smear but can be differentiated in the microbiology laboratory.

#### Recommended Regimen

- Ceftriaxone 25 to 50 mg/kg IV or IM in a single dose, not to exceed 125 mg

Topical antibiotic therapy alone is inadequate and is unnecessary if systemic treatment is administered.

### Other Management Considerations

Simultaneous infection with *C. trachomatis* should be considered when a patient does not improve after treatment. Both mother and infant should be tested for chlamydial infection at the same time that gonorrhea testing is conducted (see the CDC guideline Chlamydial Infections). Ceftriaxone should be administered cautiously to hyperbilirubinemic infants, especially those born prematurely.

### Follow-Up

Infants who have gonococcal ophthalmia should be hospitalized and evaluated for signs of disseminated infection (e.g., sepsis, arthritis, and meningitis). One dose of ceftriaxone is adequate therapy for gonococcal conjunctivitis.

### Management of Mothers and Their Sex Partners

The mothers of infants who have gonococcal infection and the mothers' sex partners should be evaluated and treated according to the recommendations for treating gonococcal infections in adults (see Gonococcal Infections in Adolescents and Adults, above).

### DGI and Gonococcal Scalp Abscesses in Newborns

Sepsis, arthritis, and meningitis (or any combination of these conditions) are rare complications of neonatal gonococcal infection. Localized gonococcal infection of the scalp can result from fetal monitoring through scalp electrodes. Detection of gonococcal infection in neonates who have sepsis, arthritis, meningitis, or scalp abscesses requires cultures of blood, cerebrospinal fluid (CSF), and joint aspirate on chocolate agar. Specimens obtained from the conjunctiva, vagina, oropharynx, and rectum that are cultured on gonococcal selective medium are useful for identifying the primary site(s) of infection, especially if inflammation is present. Positive Gram-stained smears of exudate, CSF, or joint aspirate provide a presumptive basis for initiating treatment for *N. gonorrhoeae*. Diagnoses based on Gram-stained smears or presumptive identification of cultures should be confirmed with definitive tests on culture isolates.

#### Recommended Regimens

- Ceftriaxone 25 to 50 mg/kg/day IV or IM in a single daily dose for 7 days, with a duration of 10 to 14 days, if meningitis is documented  
OR
- Cefotaxime 25 mg/kg IV or IM every 12 hours for 7 days, with a duration of 10 to 14 days, if meningitis is documented

### Prophylactic Treatment for Infants Whose Mothers Have Gonococcal Infection

Infants born to mothers who have untreated gonorrhea are at high risk for infection.



### *Recommended Regimen in the Absence of Signs of Gonococcal Infection*

- Ceftriaxone 25 to 50 mg/kg IV or IM, not to exceed 125 mg, in a single dose

### *Other Management Considerations*

Both mother and infant should be tested for chlamydial infection.

### *Follow-Up*

Follow-up examination is not required.

### *Management of Mothers and Their Sex Partners*

The mothers of infants who have gonococcal infection and the mothers' sex partners should be evaluated and treated according to the recommendations for treatment of gonococcal infections in adults (see Gonococcal Infections, above).

### Gonococcal Infections among Children

Sexual abuse is the most frequent cause of gonococcal infection in pre-adolescent children (see the CDC guideline Sexual Assault and STDs). For preadolescent girls, vaginitis is the most common manifestation of this infection; gonococcal-associated PID after vaginal infection is likely less common in preadolescents than adults. Among sexually abused children, anorectal and pharyngeal infections with *N. gonorrhoeae* are common and frequently asymptomatic.

### *Diagnostic Considerations*

Because of the legal implications of a diagnosis of *N. gonorrhoeae* infection in a child, culture remains the preferred method for diagnosis. Gram stains are inadequate for evaluating prepubertal children for gonorrhea and should not be used to diagnose or exclude gonorrhea. NAATs for the detection of *N. gonorrhoeae* can be used under certain circumstances (see the CDC guideline Sexual Assault and STDs).

### *Recommended Regimens for Children Who Weigh >45 kg*

- Treat with one of the regimens recommended for adults (see Gonococcal Infections, above)

### *Recommended Regimens for Children Who Weigh ≤45 kg and Who Have Uncomplicated Gonococcal Vulvovaginitis, Cervicitis, Urethritis, Pharyngitis, or Proctitis*

- Ceftriaxone 125 mg IM in a single dose

### *Recommended Regimen for Children Who Weigh ≤45 kg and Who Have Bacteremia or Arthritis*

- Ceftriaxone 50 mg/kg (maximum dose: 1 g) IM or IV in a single dose daily for 7 days

### *Recommended Regimen for Children Who Weigh >45 kg and Who Have Bacteremia or Arthritis*

- Ceftriaxone 50 mg/kg IM or IV in a single dose daily for 7 days

### *Follow-Up*

Follow-up cultures are unnecessary if ceftriaxone is used.

### *Other Management Considerations*

Only parenteral cephalosporins (i.e., ceftriaxone) are recommended for use in children; cefotaxime is approved for gonococcal ophthalmia only. No data are available regarding the use of oral cefixime to treat gonococcal infections in children.

All children found to have gonococcal infections should be evaluated for coinfection with syphilis and *C. trachomatis*. (For a discussion of concerns regarding sexual assault, refer to the CDC guideline Sexual Assault and STDs).

### *Ophthalmia Neonatorum Prophylaxis*

To prevent gonococcal ophthalmia neonatorum, a prophylactic agent should be instilled into the eyes of all newborn infants; this procedure is required by law in most of states. All of the recommended prophylactic regimens in this section prevent gonococcal ophthalmia. However, the

efficacy of these preparations in preventing chlamydial ophthalmia is less clear, and they do not eliminate nasopharyngeal colonization by *C. trachomatis*. The diagnosis and treatment of gonococcal and chlamydial infections in pregnant women is the best method for preventing neonatal gonococcal and chlamydial disease. Not all women, however, receive prenatal care. Ocular prophylaxis is warranted for neonates, because it can prevent sight-threatening gonococcal ophthalmia and because it is safe, easy to administer, and inexpensive.

#### Recommended Regimens

- Erythromycin (0.5%) ophthalmic ointment in each eye in a single application

This preparation should be instilled into both eyes of every neonate as soon as possible after delivery. Ideally, ointment should be applied using single-use tubes or ampules rather than multiple-use tubes. If prophylaxis is delayed (i.e., not administered in the delivery room), a monitoring system should be established to ensure that all infants receive prophylaxis. All infants should be administered ocular prophylaxis, regardless of whether they are delivered vaginally or by cesarean section.

Erythromycin is the only antibiotic ointment recommended for use in neonates. Silver nitrate and tetracycline ophthalmic ointment are no longer manufactured in the United States, bacitracin is not effective, and povidone iodine has not been studied adequately. If erythromycin ointment is not available, infants at risk for exposure to *N. gonorrhoeae* (especially those born to a mother with untreated gonococcal infection or who has received no prenatal care) can be administered ceftriaxone 25 to 50 mg/kg IV or IM, not to exceed 125 mg in a single dose.

## Clinical Algorithm(s)

None provided

## Scope

## Disease/Condition(s)

Gonorrhea and other gonococcal infections, including:

- Quinolone-resistant *Neisseria gonorrhoeae* infection
- Gonococcal infection of the cervix, urethra, rectum, and pharynx
- Gonococcal conjunctivitis
- Disseminated gonococcal infection (DGI)
- Gonococcal meningitis and endocarditis
- Ophthalmia neonatorum
- Gonococcal scalp abscess in newborns

## Guideline Category

Diagnosis

Evaluation

Management

Prevention

Screening

Treatment

## Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Pediatrics

Preventive Medicine

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Public Health Departments

## Guideline Objective(s)

### 2010 Guideline

- To update the Sexually Transmitted Diseases Treatment Guidelines 2006
- To assist physicians and other health-care providers in preventing and treating sexually transmitted diseases

### 2012 Addendum

- To describe laboratory evidence of declining cefixime susceptibility among urethral *Neisseria gonorrhoeae* isolates collected in the United States during 2006–2011
- To update the Center for Disease Control and Prevention's (CDC's) current recommendations for treatment of gonorrhea

## Target Population

- Adolescents and adults with gonococcal infection and their sex partners
- Newborns, infants, and children with gonococcal infection

## Interventions and Practices Considered

### Diagnosis/Screening

1. Screening of sexually active women at high risk for sexually transmitted diseases
2. Screening of pregnant women
3. Culture and antimicrobial sensitivity testing of gonococci isolates in patients with resistance to treatment and in cases of infections in newborns and children
4. Testing of endocervical, vaginal, urethral (men only), or urine specimens using culture, nucleic acid hybridization tests, and nucleic acid amplification tests (NAATs)
5. Gram-stained smears of exudate, cerebrospinal fluid, or joint aspirate for disseminated gonococcal infection confirmed on culture

## Management/Treatment

1. Intramuscular ceftriaxone plus oral azithromycin or doxycycline
2. Alternative regimens: oral cefixime plus oral azithromycin or doxycycline and test-of-cure; oral azithromycin and test-of-cure for those with severe cephalosporin allergy
3. Prophylactic treatment of ophthalmia neonatorum with erythromycin ophthalmic ointment
4. Treatment for associated disorders, including disseminated gonococcal infection, gonococcal meningitis and endocarditis, and gonococcal scalp abscess in newborns
5. Management of sex partners
6. Follow-up

## Major Outcomes Considered

### 2010 Guideline

- Sensitivity and specificity of diagnostic tests
- Prevalence of fluoroquinolone-resistant *Neisseria gonorrhoeae*
- Efficacy of antibiotic therapy

### 2012 Addendum

Cefixime susceptibility among urethral *N. gonorrhoeae* isolates

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Not stated

### Number of Source Documents

Not stated

### Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

### Rating Scheme for the Strength of the Evidence

Not applicable

### Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Beginning in 2008, Centers for Disease Control and Prevention (CDC) staff members and public- and private-sector experts knowledgeable in the field of sexually transmitted diseases (STDs) systematically reviewed literature using an evidence-based approach (e.g., published abstracts and peer-reviewed journal articles), focusing on the common STDs and information that had become available since publication of the 2006 *Guidelines for Treatment of Sexually Transmitted Diseases*. CDC staff members and STD experts developed background papers and tables of evidence that summarized the type of study (e.g., randomized controlled trial or case series), study population and setting, treatments or other interventions, outcome measures assessed, reported findings, and weaknesses and biases in study design and analysis. CDC staff then developed a draft document on the basis of this evidence-based review.

## Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

## Description of Methods Used to Formulate the Recommendations

### 2010 Guideline

Centers for Disease Control and Prevention (CDC) staff members and invited consultants (including public- and private-sector professionals knowledgeable in the treatment of patients with sexually transmitted diseases [STDs]) assembled in Atlanta, Georgia, in April 2009, for a meeting where all evidence from the literature reviews pertaining to STD management was discussed.

Specifically, participants identified key questions regarding STD treatment that emerged from the literature reviews and discussed the information available to answer those questions. Discussion focused on four principal outcomes of STD therapy for each individual disease: 1) treatment of infection based on microbiologic eradication, 2) alleviation of signs and symptoms 3) prevention of sequelae, and 4) prevention of transmission. Cost-effectiveness and other advantages (e.g., single-dose formulations and directly observed therapy [DOT]) of specific regimens also were discussed. The consultants then assessed whether the questions identified were relevant, ranked them in order of priority, and answered the questions using the available evidence. In addition, the consultants evaluated the quality of evidence supporting the answers on the basis of the number, type, and quality of the studies.

### 2012 Addendum

During September–December 2011, CDC and five external Gonococcal Isolate Surveillance Project (GISP) principal investigators, each with *Neisseria gonorrhoeae*-specific expertise in surveillance, antimicrobial resistance, treatment, and antimicrobial susceptibility testing, reviewed antimicrobial susceptibility trends in GISP through August 2011 to determine whether to update CDC's current recommendations for treatment of uncomplicated gonorrhea.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Peer Review

## Description of Method of Guideline Validation

Not stated

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

Throughout this guideline document, the evidence used as the basis for specific recommendations is discussed briefly. More comprehensive, annotated discussions of such evidence will appear in background papers that will be published in a supplement issue of the journal *Clinical Infectious Diseases*.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

- Appropriate screening and management of gonococcal infection
- Prevention of transmission of gonococcal infection to sex partners and newborns

### Potential Harms

- Reactions to first generation cephalosporins occur in approximately 5% to 10% of persons with a history of penicillin allergy and occur less frequently with third-generation cephalosporins.
- Ceftriaxone should be administered cautiously to hyperbilirubinemic infants, especially those born prematurely.

## Contraindications

### Contraindications

In persons with a history of penicillin allergy, the use of cephalosporins should be contraindicated only in those with a history of a severe reaction to penicillin (e.g., anaphylaxis, Stevens Johnson syndrome, and toxic epidermal necrolysis).

## Qualifying Statements

### Qualifying Statements

These recommendations should be regarded as a source of clinical guidance and not prescriptive standards; health-care providers should always consider the clinical circumstances of each person in the context of local disease prevalence. The recommendations are applicable to various patient-care settings, including family planning clinics, private physicians' offices, managed care organizations, and other primary-care facilities. These guidelines focus on the treatment and counseling of individual patients and do not address other community services and interventions that are essential in sexually transmitted disease (STD)/human immunodeficiency virus (HIV) prevention efforts.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.



## Implementation Tools

Mobile Device Resources

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents and Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Staying Healthy

### IOM Domain

Effectiveness

## Identifying Information and Availability

### Bibliographic Source(s)

Centers for Disease Control and Prevention (CDC). Gonococcal infections. In: Sexually transmitted diseases treatment guidelines, 2010 [Erratum appears in MMWR Recomm Rep. 2011 Jan 14;60(1):18]. MMWR Recomm Rep. 2010 Dec 17;59(RR-12):49-55.

Centers for Disease Control and Prevention (CDC). Update to CDC's sexually transmitted diseases treatment guidelines, 2010: oral cephalosporins no longer a recommended treatment for gonococcal infections. MMWR Morb Mortal Wkly Rep. 2012 Aug 10;61:590-4. [11 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2010 Dec 17 (addendum released 2012 Aug 10)

### Guideline Developer(s)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

## Source(s) of Funding

United States Government

## Guideline Committee

Not stated

## Composition of Group That Authored the Guideline

### 2010 Guideline

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## 2012 Addendum

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## Financial Disclosures/Conflicts of Interest

Not stated

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

### 2010 Guideline

Electronic copies: Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#) .

### 2012 Addendum

Electronic copies: Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#) .

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

## Availability of Companion Documents

The following are available:

- The Centers for Disease Control and Prevention (CDC) sexually transmitted diseases (STD) treatment guidelines, 2010. eBook for iPad, iPhone, and iPod Touch. Available from the [CDC Web site](#) .
- 2010 STD treatment guidelines webinar: an overview by CDC and the National Network of STD/HIV Prevention Training Centers (NNPTC), including continuing medical education (CME) activity. Available from the [CDC Web site](#) . Slides from the webinar are also available from the [CDC Web site](#) .
- Sexually transmitted diseases treatment guidelines, 2010. Podcast. Available from the [CDC Web site](#) .

## Patient Resources

None available

## NGC Status

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